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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,200	04/09/2004	Gerald P. Schatten	48631-00004	8230

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EXAMINER	
TON, THAIAN N	
ART UNIT	**PAPER NUMBER**
1632	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,200	SCHATTEN ET AL.	
	Examiner	Art Unit	
	Thaian N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-16,21-23,28-49 and 67-86* is/are pending in the application.

4a) Of the above claim(s) *22,23,28-49 and 67-84* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13-16,21,85 and 86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *11/14/07*.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/16/07 has been entered.

Applicants filed no remarks or claim amendments with the RCE request. The after-final amendment, filed 7/16/07, has been entered. The Examiner addresses the Remarks filed concurrently with the after final amendment. Claims 1, 13 are amended; claim 12 is cancelled; claims 22, 23, 28-49, 67-84 are withdrawn; claim 86 is newly added; claims 1-11, 13-16, 21, 85 and 86 are under current examination.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-21, 24-27, 50-66) in the reply filed on 6/1/06 is acknowledged. The requirement is still deemed proper and is therefore made FINAL.

Claims 22, 23, 28-49, 67-84 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/1/06.

This application contains claims 22, 23, 28-49, 67-84 drawn to an invention nonelected with traverse in the reply filed on 6/1/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 13-16, 21, 85 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim1, 10, 34-53 of copending Application No. 11/003,006 in view of Campbell (of record).

Applicants maintain that the Examiner's rejection is improper for the reasons stated previously. Applicants request to defer addressing the present rejection until allowable subject matter is indicated. See page 7 of the Response.

These arguments are not sufficient to overcome the rejection of record, therefore it is maintained.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, 13-16, 21, 85 and 86 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for reasons of record, advanced in the prior Office actions.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Applicants' Arguments. Applicants argue that the Examiner has erred with regard to the requirement of the claims to produce a cloned animal. Applicants argue that they have now deleted the language "producing a cloned animal" and that the Examiner has proceeded to interpret "viable primate embryo" to require the production of a cloned animal. See page 8 of the claim.

Additionally, Applicants argue that Examiner not only misinterpreted "viable primate embryo", but by reference to its possible uses, the Examiner only considered the use of the embryo to produce a cloned animal. Applicants argue that this "twisted reasoning" led the Examiner to read the language of producing a cloned animal, back into her analysis, and thus, creating the straw man necessary for the Examiner to improperly reject the claimed invention. See page 9 of the Response.

Applicants further argue that the term viable has an accepted meaning in the art, such as "capable of living," and that the Examiner ignores this ordinary meaning of "viable". Additionally, the express definition of "embryo" in the specification is a developing cell mass that has not been implanted in the uterine membrane. Thus, Applicants argue that a "viable primate embryo" is one that is a developing cell mass that is capable of living. Applicants argue that there nothing in this meaning that requires the production of a cloned animal, and that the Examiner must give credence to Applicants' own definition, which is explicitly inapposite to the Examiner's position.

Response To Arguments. These arguments have been considered but are not persuasive. The Examiner maintains the prior rejection for the following reasons: the claimed invention has been examined only to the extent that it reads upon apps' elected invention (*i.e.*, methods of producing a cloned animal). Additionally, the specification provides a definition for the term "embryo" at ¶ 32, as stated by Applicants; however, this citation does not provide any guidance for a "viable" primate embryo, which is required by the claims. Applicants' definition of "viable" has been noted but is not persuasive. It is unclear what the enabled use of an embryo that is "capable of living" would have, in the context of the claimed invention. In particular, it appears that the only contemplated uses for the embryos that are produced by the claimed methods are either for the production viable, cloned primates, or to use the viable embryos to produce embryonic stem cells (see, for example, p. 14, ¶55). The specification teaches that spindle organization and accurate segregation of chromosomes are required for the production of viable primate embryos, as evidenced by the non-viability of embryos prepared by NT that lack structural or motile molecules form the sperm centrosomes (see p. 11, ¶46). Thus, although the claims recite the production of a viable primate embryo, the only contemplated uses for these viable embryos are in either the production of embryonic stem cells, or the production of viable primates. The Examiner has

addressed the unpredictability in producing viable, cloned primates previously. Additionally, with regard to Applicants' arguments that the art of Ng and Chen do not provide predictability in producing viable, primate embryos, with regard to the removal of the mitotic spindle, the Examiner reiterates that these references show that, even post-filing, it would not be predictable to produce a viable, primate embryo.

Applicants have provided Zhou to show that NuMA turbulence associated with disordered chromosome organization found in some SCNT-produced embryos in this study was consistent with development failure. Zhou is not within the context of the claimed invention, which is broadly directed to introduction of a centrosomal component from a sperm chromosome with a primate cell nucleus, in nuclear transfer methods because Zhou does not discuss the addition of a centrosomal component from sperm centrosome with a primate cell nucleus. Additionally, Applicants have misrepresented the data presented by Zhou. On page 2568, col. 1-2, Zhou discuss NuMA expression, and found that a minority of SCNT 1-cell embryos were characterized by the absence of NuMA staining, and that some of the blastomeres had NuMA absence. This is not to say that all of the embryos, produced by Zhou, had the absence of NuMA, in fact, some of the embryos developed with normal NuMA staining (see p. 256, col. 2). Thus, the post-filing art of Zhou, and that of Ng (of record) fail to enable the claimed invention. The as-filed disclosure clearly teaches that there is a direct correlation between reproduction and the ability to assemble mitotic spindles (see p. 11, ¶45), and that it is observed that primate embryos prepared by NT have mitotic spindle defects. Therefore, the Ng and Zhou reference clearly shows that primate embryos, produced by NT, are capable of spindle formation. As Ng further suggest that the developmental failure in primate NT could be caused by, for example, incomplete nuclear reprogramming. This is further supported by Chen *et al.* (of record), See page 1, Introduction, col. 1-2 and additionally supported by Zhou, who show appropriate spindle formation in the

embryos. Given that the specification provides no specific guidance for the enabled use of a "viable primate embryo", and the post-filing art which clearly shows that even with appropriate spindle formation, the embryos were not capable of further development, one of skill in the art would have had to practice undue experimentation to make and use the claimed invention.

Applicants have now amended the claims to recite using a centrosomal component from a sperm centrosome, and argue that this renders the prior rejection moot (see page 11 of the Response). This amendment does not overcome the rejection, for reasons of record. In short, the working example in the specification provides no guidance to show that the introduction of a centrosomal component from a sperm centrosome would result in a viable, primate embryo. The observation that the primate embryos produced by SCNT do not form functional spindles, or that the centrosomes are missing NuMA and HSET kinsein do not provide guidance to show that addition of these proteins would correct the defect. In fact, the post filing art shows that addition of these components is not required to show spindle formation. See Chen, Ng, and Simerly, who all show spindle formation in primate embryos. However, cumulatively, none of these pieces of art provide guidance to show a viable primate embryo, with regard to the production of a viable animal.

With regard to Applicants arguments that the Examiner ignores the teachings in the specification, namely with regard to using cells of a rhesus monkey, and utilizing rhesus monkey cells in NT, the Examiner responds that it is not that one of skill, given the teachings, would not understand that one could use rhesus monkey cells in the claimed methods. The claimed methods are not enabled for reasons of record set forth here and in prior Office actions. Namely, there is no guidance to show that addition of a centrosomal component from a sperm centrosome would result in a viable primate embryo, and correct the defect of malfunctioning spindles.

Applicants argue that the Examiner does not address claim 85 in the prior enablement rejection, particularly in light of the proposed amendments to claim 1. See page 13 of the Response. The Examiner responds that this claim was analyzed previously, and the Examiner did address the breadth of donor cells previously, thus, the prior rejection of record is proper and maintained.

Applicants argue that proposed claim 86 is enabled, because the working example in the specification relates to a rhesus monkey. See page 13 of the Response. The Examiner responds that the working examples in the specification, although directed to using rhesus monkey cells, only show the activation and culture of NT constructs. However, the working examples are not within the scope of the claimed invention, because they do not relate to the addition of a centrosomal component from a sperm centrosome, along with a primate cell nucleus, to produce a viable primate embryo. This is what is required of the claimed invention. In fact, the specification teaches that the primate embryos had faulty mitotic spindles, but provides no guidance with regard to the addition of any factor in order to remedy the faulty spindles. Therefore, the working example in the specification does not provide enabling guidance for the claimed invention. Additionally, it is reiterated that the claimed invention is non-enabling for the reasons set forth in this office action, as well as the prior Office actions.

Thus, in the instant case, the specification provides no specific guidance with regard to how to make and use the claimed invention. In particular, the specification teaches the absence of specific molecular components and the observation that SCNT-produced primate embryos had faulty mitotic spindles, with regard to a specific component, NuMA. The specification provides no guidance to show that the addition of these factors would result in a viable primate embryo; furthermore, the post-filing art of Ng and Chen show that NT primate embryos are capable of spindle formation, and yet would not still be considered "viable", as required by the claims.

Accordingly, in view of the state of the art of NT, particularly with regard to the unpredictability of donor cells and recipient cells to be used, where the state of the art only supports specific cell types with regard to successful NT, the state of the art of primate NT, wherein art at the time of filing shows that improper spindle formation is perhaps not the only cause for developmental arrest of primate NT embryos, the post-filing art that shows that primate NT remains unpredictable, the lack of teachings or guidance provided by the specification, with regard to using a centrosomal component from a sperm centrosome, that would be added to the nuclei to produce a viable embryo, it would have required undue experimentation, for one of skill in the art, to determine the parameters, cell types, molecular components necessary to achieve successful SCNT, as broadly claimed.

Claim Rejections - 35 USC § 112

The prior rejection of claims 1-16, 21 and 85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in view of Applicants' amendment to the claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Thursday from 7:00 to 5:00 (Eastern Standard Time). Should the Examiner be unavailable, inquiries should be directed to Peter Paras, SPE of Art Unit 1632, at (571) 272-4517. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the Official Fax at (571) 273-8300. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Thaian N. Ton/
Primary Examiner
Art Unit 1632